PCV106

RE-HOSPITALIZATION RATES OF ACUTE CORONARY SYNDROME PATIENTS IN REAL WORLD CLINICAL PRACTICE: OBSERVATIONS FROM A NATIONAL ADMINISTRATIVE CLAIMS DATA

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OBJECTIVES: Re-hospitalization and mortality rates are increasingly being used as quality of care measures that have significant reimbursement implications. We examine the rates of re-hospitalization and mortality of acute coronary syndrome (ACS) patients in real-world clinical practice. **METHODS:** Commercially-insured patients (age >18 years) with an inpatient hospitalization for ACS [ICD-9-CM codes for acute myocardial infarction or unstable angina (UA)] between 1/1/2007-5/31/2010 were identified from medical claims in the HealthCore Integrated Research Database (HIRD). Patients with ACS events within one year prior to index hospitalization were excluded. All-cause and ACS-related re-hospitalizations and mortality rates within 30 days and 12 months after index event were evaluated. **RESULTS:** Of 66,772 ACS patients (60% male; mean age 66.6 years), 21% had diagnostic coding for ST elevation myocardial infarction (STEMI), 31% had coding for non-ST elevation myocardial infarction (NSTEMI), 37% had UA, and 11% had not otherwise specified (NOS) ACS. Approximately, 90% and 52% of patients had >30-days and > 12 months of continuous eligibility respectively. The 30-day all-cause re-hospitalization rate was 16.3 % (STEMI: 16.4%, NSTEMI: 19.0%, UA: 13.3%, NOS: 20.6%;) and 6.3 % (STEMI: 8.8%, NSTEMI: 6.6%, UA: 5.2%, NOS: 4.5%) for an ACS-related re-hospitalization. The 12-month all cause re-hospitalization rate was 41.3% (STEMI: 39.0%, NSTEMI: 46.4%, UA: 38.2%NOS: 46.6%,)and 16.6% for an ACS-related re-hospitalization. The 30-day post-index mortality rate was 2.4 % (STEMI:1 .8%, NSTEMI:4.3%, UA:0.5%, NOS:5.2%;) and the 12-month rate was 7.0%. For patients with ages > 65 years, the 30-day all-cause and ACS-related re-hospitalization rates were 21.2% and 7.0%, respectively. **CONCLUSIONS:** The re-hospitalization and mortality rate for ACS patients within 30 days and 12-months post-index hospitalization discharge as observed in real-world clinical practice remain high. Use of more effective therapies may provide an opportunity to improve important clinical and economic outcomes in ACS patients.

PCV107

IDENTIFYING EFFICIENT ACUTE CLINICAL PATHWAYS FOR CHEST PAIN: USING RISK ADJUSTED COST-EFFECTIVENESS (RAC-E) TO COMPARE HOSPITALS USING LINKED, ROUTINELY COLLECTED DATA

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OBJECTIVES: Cost-effectiveness analysis is now well established in relation to the evaluation of health technologies, but not in relation to broader institutional level variations in clinical pathways. Linked, routinely collected data provides an opportunity to evaluate real world activity. A novel approach to analysing the risk-adjusted cost-effectiveness (RAC-E) of acute services for patients presenting with chest pain at the four main public hospitals in South Australia is presented. **METHODS:** Routinely collected data on hospital separations (including costs) and mortality records were linked deterministically. Relevant intermediate endpoints over a two year follow-up period in a cohort of patients presenting with chest pain in the year to July 2006 were identified. Lifetime costs and survival were extrapolated from these endpoints using data from chest pain patients presenting between July 2002 and June 2008. The resulting estimates of costs and survival were standardized using separate regression models that estimated expected cost and survival values for each patient. **RESULTS:** In the base case, two of the four hospitals were dominated by hospital 1. Hospital 2 had lower standardized lifetime costs than hospital 1, and the incremental cost per life year gained between these two hospitals was Aus$2,909. A bootstrapped probabilistic sensitivity analysis showed hospital 1 to have very high probabilities of cost-effectiveness at relevant dollar values for a life year gained. Analysis of differences in cost components between the hospitals showed that hospital 1 spent relatively less on pathology and imaging, whilst spending more on nursing time and pharmaceuticals. **CONCLUSIONS:** RAC-E provides a useful framework for identifying important differences in the costs and benefits associated with variations in clinical practice. Potential determinants can be partially investigated with the data, but further primary analysis of clinical pathways at key hospitals is required to fully inform the dissemination of best practice.

PCV108

CARDIOVERSION TREATMENT PATTERNS AND OUTCOMES AMONG ACUTE ATRIAL FIBRILLATION PATIENTS IN 5 EUROPEAN COUNTRIES

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OBJECTIVES: We examine current treatment patterns associated with the use of antiarrhythmics for pharmacologic cardioversion and evaluate time to conversion among patients with acute atrial fibrillation (AF) in France, Italy, Germany, Spain, and UK. **METHODS:** Data were collected cross-sectionally as observed by 303 physicians from April to June 2010. **RESULTS:** Among 2,997 patients, 1,352 (45%) received pharmacologic cardioversion only, with 1,082 (80%) successfully cardioverting. Of these, 931 (69% of those treated pharmacologically, 86% of those successfully) had complete information on time to achieve sinus rhythm and were further assessed here. Amiodarone was administered to most (49%), with similar proportions receiving intravenous (IV) (53%) and oral (46%) formulations. Amiodarone IV was associated with a significantly shorter median conversion time (8 hours) compared to oral (36 hours). Patients treated with flecainide (26%) had the shortest median time to cardioversion (4 hours), while patients on propafenone (15%) were next (6 hours). Median cardioversion time varied by country. Specifically, patients in France took longer to convert on amiodarone IV and oral at a median time of 12 and 48 hours compared to an average of 7 and 24 hours, respectively, in other countries. In Germany, little difference was observed with median conversion times of 9 and 10 hours for amiodarone IV and oral, respectively. Median conversion times were also similar between amiodarone IV and flecainide in Spain and Italy (a difference of 1 and 2 hours, respectively) compared to an average difference in median conversion time of 4 hours between these treatments overall. **CONCLUSIONS:** While amiodarone had a longer median time to cardioversion, faster acting agents, such as flecainide and propafenone, had conversion times substantially longer than their known time of action, reflecting other influences on treatment administration. Differences in conversion time suggest country- and physician-specific practices in the use of pharmacologic cardioversion therapies.

Cardiovascular Disorders – Research on Methods

PCV109

BEYOND CASE FATALITY: A NEW METHOD TO ESTIMATE THE EFFECT OF INCREASING TREATMENT UPTAKE ON MORTALITY

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OBJECTIVES: Epidemiological models have been widely used to estimate how increased uptakes of medical and surgical treatments affect mortality and related outcomes. Standard methods rely on the estimate of the case fatality, defined as the risk of death in the absence of the treatment. Because most patients receive some treatment, mortality rates where some treatment is present are often used instead of case fatality rates, leading to biased results. A method that does not rely on case fatality estimates is needed. **METHODS:** We borrow the mechanism used for the calculation of the Potent Impact Fraction (PIF), an epidemiological measure that is equal to the proportional reduction in the incidence of a disease or mortality, resulting from a specific change in the distribution of a risk factor in the population, and apply it to the estimation of the *relative* reduction of mortality caused by the increase of treatment uptake in the population at risk. We apply this method to estimate the reduction of cardiovascular disease deaths in Ontario, if treatment rates for CHD interventions were to be increased from 2005 levels to the recommended benchmark utilization of 90%. The Mant-Hicks model for polypharmacy is adopted, while the uptakes of multiple treatments are assumed to be independent from each other. **RESULTS:** Using the proposed PIF-based method, we estimated that increasing treatment to benchmark levels uptake results in a reduction of cardiovascular mortality of 22.5%. The standard method gives a reduction of 17%, probably due to underestimation of the case fatality. **CONCLUSIONS:** Here we present an alternative method for the estimation of the effect of treatment uptake increase to the reduction of mortality. Our example suggests that the magnitude of bias associated with the standard method may be substantial. This approach may be a useful tool for epidemiological and health care research.

PCV110

DEVELOPMENT AND VALIDATION OF A SHORT PRO MEASURE OF HEALTH STATUS FOR INDIVIDUALS WITH ACUTE MYOCARDIAL INFARCTION: THE MYOCARDIAL INFARCTION DIMENSIONAL ASSESSMENT SCALE (MIDAS)

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OBJECTIVES: To develop and validate a disease-specific health status measure for individuals with myocardial infarction (MI). **METHODS:** The development of the Myocardial Infarction Dimensional Assessment Scale (MIDAS) followed three main stages. Stage 1 consisted of in-depth, semi-structured, exploratory interviews conducted on a sample of 31 patients to identify areas of salience and concern to patients with MI. These interviews generated 48 candidate questions. In stage 2 the 48-item questionnaire was used in a postal survey to identify appropriate rephrasing/shortening, to determine acceptability and to help identify sub-scales of the instrument addressing different dimensions of MI. Finally, in stage 3 the construct validity of MIDAS subscales was examined in relation to clinical and other health outcomes. Setting - A single centre (district general hospital) in England was used for stages 1 and 3 and a national postal survey was conducted for stage 2. Patients - A total of 410 patients were recruited for the national survey (stage 2). Full data was available on 348 (85%) patients. 155 patients were recruited to test construct validity (stage 3). **RESULTS:** The MIDAS contains 35 questions measuring seven areas of health status: physical activity, insecurity, emotional reaction, dependency, diet, concerns over medication and side effects. The measure has high face, internal and construct validity and is likely to prove useful in the evaluation of treatment regimes for MI. **CONCLUSIONS:** The MIDAS has acceptable validity and reliability. It is suitable for use in a variety of settings for patients with myocardial infarction.

PCV111

IDENTIFICATION OF RESPONSE SHIFT AMONG HYPERTENSIVE PATIENTS WITH CORONARY ARTERY DISEASE USING TWO STRUCTURAL EQUATION MODELING TECHNIQUES

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OBJECTIVES: To identify response shift using two structural equation modeling (SEM) techniques with the SF-36 Health Survey. **METHODS:** Hypertensive patients with coronary artery disease (CAD) who completed both baseline and one year follow-up of the SF-36 were included (n=909). An occurrence of response shift using Oort and Schmitt SEM techniques was specifically identified. LISREL software was used to conduct SEM procedures. A variety of fit indices were used to determine model fit. For both SEM approaches, response shift is defined based on changes in various parameters in the measurement model. Effect size indices were calculated for the contribution of response shift on the change of SF-36 domains scores. We hypothesized the divergence in defining type of response shift linked to changes in various parameters will lead to different findings. **RESULTS:** Only the SF-36 physical functioning (PF) scale was identified with recalibration response shift by using both Oort and Schmitt SEM approaches. With Oort approach, recalibration was identified by the change in intercepts, whereas Schmitt approach defines recalibration as the change in factor variances or factor loadings over time. Effect size of the recalibration response shift on the change of PF domain scores was marginal: −0.118. **CONCLUSIONS:** This is the first study to identify response shift in hypertensive CAD patients using SEM approach. Recalibration response shift was identified using both Oort and Schmitt SEM approaches. Different interpretation of specific PF items by hypertensive CAD patients before and after treatments may contribute to the recalibration response shift. By looking more closely at the SF-36 PF domain scores among hypertensive CAD patients will enable us to provide nuanced attention and direct treatment for the most impaired aspects of quality of life.

PCV112

EXTENSION OF META-ANALYSIS IN COMPARING OF FIMASARTAN WITH LOSARTAN IN BLOOD PRESSURE LOWERING EFFECT

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OBJECTIVES: A new drug fimasartan had been developed and currently approved in Korea for treating essential hypertension. This study aimed to identify whether main results of direct comparative study maintains consistency with those of extension of meta-analysis in the blood pressure lowering effect of fimasartan with losartan. **METHODS:** Systematic reviews of literatures of clinical trials including fimasartan or losartan were conducted. The blood pressure change from baseline were used as an effectiveness measure and was pooled in RevMan 4.0. For direct comparison, the head-to-head randomized controlled trial (RCT) of fimasartan and losartan was used. For indirect comparison, it followed to method of adjusted indirect comparison (Bucher 1997) using common comparator and used ITC (Indirect Treatment Comparison) program (CADTH). In addition, Bayesian mixed treatment comparison (MTC) was performed on which combines whole pairwise comparison studies together by WinBugs program. After that, the results were compared with that of a direct comparison. **RESULTS:** In regard to direct comparison, there is the only head-to-head trial (Phase III) report of comparing fimasartan with losartan, which had conducted locally. For indirect comparison, the search identified one report of the trial of comparing fimasartan with placebo (Phase IIb), and the 6 of articles of comparing losartan with placebo were selected and measured estimates were pooled. The change in reduction in diastolic blood pressure of losartan and fimasartan versus placebo was −2.7 mmHg as direct estimate retrieved from RCT, and −3.315 mmHg as combined estimate through MTC analysis, respectively. In SBP reduction, it was −4.3 mmHg and −3.995 mmHg respectively. **CONCLUSIONS:** This study found that estimates obtained from indirect comparison were similar with those of direct. The results from the two comparison methods both indicated consistently that the antihypertensive effect of fimasartan is better than losartan.

Sensory Systems Disorders – Clinical Outcomes Studies

PSS1

STEVENS-JOHNSON AND RED MAN SYNDROME: A CASE REPORT ON ADVERSE DRUG REACTIONS OF SIMULTANEOUS USE OF PHENYTOIN AND VANCOMYCIN

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OBJECTIVES: Adverse drug reactions (ADRs) are a common cause of injury to hospitalized patients and are likely preventable. Monitoring spontaneous adverse drug reactions is one of the epidemiological methods for assessing the safety of drugs in a hospital setting. Many studies reported that cutaneous reactions and gastrointestinal disturbances as top most reported ADRs. **METHODS:** The author reports a case of 22-year-old girl who developed Stevens-Johnson syndrome and Red Man syndrome after receiving phenytoin and vancomycin simultaneously. **RESULTS:** This was 22 year old girl presented with chief complaints of headache, nausea, vomiting and sweating. Diagnosed as a case of post fossa tumor and operated on 3rd day after admission. She was treated with different medications along with vancomycin 1gm 12hourly, phenytoin 100mg 8 hourly and dexamethasone 2gm 8 hourly. On the day 15 of vancomycin and phenytoin treatment, the patient developed diffuse polymorphic erythema with mouth lesions and typical palmo-plantar lesions characteristic of Stevens-Johnson syndrome. Also a skin rash and lesions predominantly on the face, neck, upper back and front regions characterized as Red Man syndrome. Use of vancomycin and phenytoin was discontinued and replaced by cefipime plus linizolid and phenobarbitone respectively. The reaction persisted for approximately 55 days with progressive improvement and the patient was treated with hydroxyzine 30mg, 6 hourly, hydrocortisone 100mg, 6 hourly with gradual tapering of the dose and topical treatment of the lesions. **CONCLUSIONS:** Although there are reports on the of adverse drug reaction with monotherapy of phenytoin and vancomycin or in involvement with other medications. However, there are no reports on the development of Stevens-Johnson and Red man syndrome when phenytoin and vancomycin were used simultaneously with other drug treatment. It also confirms the possible increased risk of developing Stevens-Johnson syndrome when phenytoin is associated to corticosteroids.

PSS2

DIAGNOSED AND UNDIAGNOSED DRY EYE, SYMPTOM SEVERITY, AND ASSOCIATED FACTORS AMONG MEN AND WOMEN IN THE UNITED STATES

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OBJECTIVES: To examine factors associated with dry eye disease (DED) in the US. **METHODS:** We conducted a cross-sectional survey of 4000 participants in the Women's Health Study and Physicians' Health Studies with diagnosed DED or severe symptoms. We assessed the current level of symptoms by the Ocular Surface Disease Index (OSDI) and Symptom Assessment in Dry Eye (SANDE) questionnaires, diagnosis, co-morbidities, treatments, and patient satisfaction. **RESULTS:** 3390 (84.8%) subjects returned questionnaires. 2099 participants reported a diagnosis of DED, and 1291 denied DED diagnosis (73.9% of these had reported DED diagnosis previously). Among 451 subjects selected based on severe symptoms alone, 114 (25.3%) reported a new diagnosis of DED, which was more strongly associated with severe symptoms by SANDE>40 (OR=2.24, p=0.001), than by OSDI 33-100 (OR=1.38, p=0.25). Blepharitis (OR=2.03, p=0.05) was also associated with new DED diagnoses. Among those who currently denied DED diagnosis, 15.9% had severe (SANDE>40) and 40.4% had mild-moderate symptoms (SANDE 15-40). Adjusting for age and sex, participants with symptoms only were less likely than diagnosed patients to have an eye exam ≥1x/year (OR=0.71, p=0.002), use antidepressants (OR=0.76, p=0.04), artificial tears (OR=0.67, p=0.0002), or other DED treatments (OR=0.65, p=0.0001); and more likely to report refractive surgery (OR=1.67, p=0.02), and contact lens wear (OR=2.51, p<0.0001). In age- and sex-adjusted models including all respondents, those who currently reported DED diagnoses were more likely to have an eye exam ≥1x/year (OR=1.42, p=0.0003), severe symptoms (SANDE >40, OR=2.00, p<0.0001), blepharitis (OR=1.41, p=0.007), use antidepressants (OR=1.43, p=0.003), artificial tears (OR=2.01, p<0.0001), or other DED treatments (OR=1.70, p<0.0001); and less likely to use glaucoma medications (OR=0.82, p=0.02). **CONCLUSIONS:** These observations suggest the possibility of under-diagnosis of DED, and are also consistent with a milder and/or more intermittent type of DED. Individuals with diagnosed DED are more likely to have severe symptoms, despite therapy.

PSS3

PERSISTENCE WITH STATINS AND THE RISK OF AGE RELATED MACULAR DEGENERATION IN A LARGE HEALTH ORGANIZATION IN ISRAEL

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OBJECTIVES: To investigate the association between persistent use of statins and the risk of age-related macular degeneration (AMD). **METHODS:** A population-based retrospective cohort among adults who began statin therapy between 1998 and 2006 in a large health organization in Israel. The organization's central computerized databases were used to collect sata on incident AMD cases diagnosed by ophthalmologists. **RESULTS:** A total of 108,973 individuals aged 55 or older were identified. During the study follow-up period 409,113 person-years, there were 2,732 incident AMD cases (6.68 per 1,000 person-years). The crude incidence density rate of AMD among patients at the lowest quintile of persistence with statins (7.18 per 1,000) was comparable to that of highest persistence quintile (7.13 per 1,000). After adjustment for potential confounders, patients in the highest quintile of persistence with statins had a hazard ratio of 0.99 (95% CI: 0.78-1.26) for AMD compared with patients in the lowest PDC quintile. In addition to age, AMD was found to associate with past smoking, asthma, diabetes and frequent visits to ophthalmologists or primary physicians prior to index date. **CONCLUSIONS:** Our study agrees with previous studies that showed no association between persistent use of statins and reduced risk of AMD. These results suggest that the early reports on a strong protective effect of statins against AMD development, were probably a result of a small study effect.

PSS4

SYSTEMATIC REVIEW OF THE EPIDEMIOLOGIC LITERATURE ON ATOPIC DERMATITIS IN CHILDREN

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OBJECTIVES: A systematic review of the literature was performed to gather the epidemiological evidence related to atopic dermatitis (AD) in a pediatric population. **METHODS:** OVID MEDLINE® was searched using terms related to AD, epidemiology, incidence/prevalence in a population ≤18 years old. Two researchers undertook the inclusion/exclusion process on the 466 citations that had been identified. A third person acted as an overall reviewer and adjudicator. **RESULTS:** The major finding was the International Study of Asthma and Allergies in Childhood (ISAAC) which reported the prevalence of AD in children 6-7 years old from 35 countries at two distinct time periods (around 1995 and 2002). A further 32 independent studies were identified for inclusion in this review. These studies reported on incidence (n=2), prevalence (n=25) or both (n=5) in Europe (n=23), Southeast Asia (n=8) and Africa (n=1). The number of study participants differed greatly (n=137 to n=317,926). According to ISAAC, the worldwide prevalence rate of AD increased by a rate of 36% from 12.9% in 1995 to 17.5% in 2002. Over that same time period, a 46% increase was reported for North America and Western Europe with